Prospective randomized study to compare between the effect of sleeve gastrectomy and mini-gastric bypass on nonalcoholic steatohepatitis in morbidly obese patients

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Received: 25 July 2021
Accepted: 29 August 2021
Published: xx Month 2021

The Egyptian Journal of Surgery 2021, 40:1357–1364

Background
Most of morbidly obese patients have a variety of metabolic diseases. One of them is nonalcoholic fatty liver diseases); therefore, bariatric procedures like sleeve and mini-gastric bypass (MGB) help in significant weight reduction that may help in improving liver condition.

Patients and methods
The study was conducted at Bariatric Surgery Department of Ain Shams University Hospitals during the period from November 2018 to December 2020. It included 30 patients who were morbidly obese and had nonalcoholic steatohepatitis proved by liver biopsy taken intraoperative. In total, 14 patients underwent laparoscopic-sleeve gastrectomy and 16 patients underwent laparoscopic MGB.

Results
There was significant improvement in both controlled attenuation parameter (CAP) and kilopascals (kPa) after 1 year in both bariatric procedures. CAP declined in sleeve from 323.93±37.09 to 253.79±18.36 with *P* value of 0.000 and in bypass declined from 345.06±35.14 to 249.31±13.96 with *P* value of 0.000. kPa declined in sleeve from 8.85±2.73 to 6.96±2.19 and in bypass patients declined from 10.40 ±2.52 to 7.48±1.92 with *P* value of 0.000, with superiority for MGB over sleeve in both CAP and kPa with *P* value of 0.041 and 0.006, respectively.

Conclusion
The results of our study suggest that laparoscopic-sleeve gastrectomy and MGB are associated with significant improvement in liver steatosis and fibrosis with significant superiority for MGB over sleeve and FibroScan might be a useful adjunct to evaluate the effects of bariatric surgery on liver steatosis and fibrosis.

Keywords:
bypass, FibroScan, nonalcoholic steatohepatitis, sleeve

Egyptian J Surgery 40:1357–1364

1110-1121

Introduction

Nonalcoholic steatohepatitis (NASH) is one of morbid obesity problems that is characterized by abnormal fat deposition in liver cells and is the most common chronic liver disease all over the world [1].

NASH may lead to cirrhosis in ~20% of patients, and NASH-related cirrhosis is considered a major cause of cryptogenic cirrhosis and liver-related death [2].

The development process of nonalcoholic fatty liver disease (NAFLD) can start from simple steatosis (NAFLD) to NASH and eventually leads to cirrhosis and HCC in the absence of excessive alcohol intake [3].

Surgical treatment of morbid obesity results in significant sustained weight loss, which reduces obesity-related morbidity and increases survival compared with patients receiving optimal medical therapy [4].

Several studies have reported changes in hepatic histology from liver biopsies obtained at the time of bariatric surgery and after weight loss. Previous reviews have documented that hepatic histology improves in most obese patients with NAFLD and NASH who undergo bariatric surgery using current techniques [5].

Aim

The aim of this prospective study is to compare the effect of two bariatric surgery procedures: sleeve gastrectomy and mini-gastric bypass (MGB) on NASH after 1-year postoperative follow-up.

DOI: 10.4103/ejs.ejs_236_21

Patients and methods

The study was conducted at the Bariatric Surgery Department of Ain Shams University Hospitals during the period from November 2018 to December 2020. This research was performed at the Department of General Surgery, Ain Shams University Hospitals. Ethical Committee approval and written, informed consent were obtained from all participants. It included 30 patients who were morbidly obese and had NASH proved by liver biopsy taken intraoperative.

All cases were operated by or under supervision of consultant surgeons at the Bariatric Surgery Unit at Ain Shams University. An informed consent was taken from all the patients who accepted to participate.

This study included two groups of patients:

Group A composed of 14 morbidly obese patients who underwent sleeve gastrectomy in the bariatric unit having NASH proved by histopathology.
Group B composed of 16 patients who underwent MGB in the bariatric unit having NASH proved by histopathology.

Inclusion criteria

Fit for surgery. Adult male or female patients, age 18–60 years. Patients who had NASH by clinical criteria (absence of significant alcohol use, fatigue and malaise, hepatosplenomegaly, and truncal obesity) and liver biopsy.

Exclusion criteria

Generally unfit for operation. Old-age patients more than 60 years. Patients with history of psychiatric illness. Patient refusal. Patients with alcoholic hepatitis or viral hepatitis.

All patients were subjected to the following.

Preoperative assessment

Full clinical history, personal history, present history, and past history, especially history of any metabolic or hepatic disorder. Full clinical examination, BMI, vital signs, and body examination. Routine preoperative investigations, including complete blood count, random blood sugar, liver-function test, kidney-function test, coagulation profile, lipid and thyroid profile, serum electrolytes, and HBA1c. ECG, echocardiography, pulmonary-function test, dye study, and upper gastrointestinal tract endoscopy if indicated.

Intraoperative

Operative management

Surgery was performed under general anesthesia. The patients were placed in supine position with the table in reverse Trendelenburg position with legs spread. Nasogastric tube was inserted.

Cases who underwent mini-gastric bypass

Creating pneumoperitoneum and port placement

After Veress needle insufflation in the left hypochondrium, the first 11-mm trocar for the camera was placed in the midpoint between the xiphoid and the umbilicus at midline. The second trocar (5 mm) was placed in the right hypochondrium at anterior axillary line; the third trocar (12 mm) was inserted in the left hypochondrium, symmetrical to the previous one. The fourth trocar (12 mm) was placed in the right quadrant at anterior clavicular line on the same level of the camera. A 5-mm incision in the subxiphoid region for hook liver retractor to elevate the left lobe of the liver.

Creation of the gastric pouch

The stomach is divided at the junction of the body and the antrum at the level of the crow's foot with 60-mm Endo-GIA stapler to get the longest possible gastric pouch.

A lesser curvature-based tube of stomach is constructed with a 60-mm linear stapler using blue cartridges (Ethicon) around an orogastric tube of 36-Fr size.

Choosing and measurement of jejunal loop

A graded grasper is used to measure about 200 cm of jejunum from the ligament of Treitz.

Creation of gastrojejunostomy

The jejunal loop brought up antecolic and anastomosed to the stomach tube with 60-mm Endo-GIA stapler. Antireflux stitch between biliary limb and gastric pouch was made to decrease biliary reflux.

The common stapling defect was closed over nasogastric tube with two layers of No 2-0 absorbable Vicryl TM suture in a running fashion.

The anastomosis was then tested with methylene blue injected through the nasogastric tube. A tube drain was left in the vicinity of the gastrojejunostomy under the left lobe of the liver.

In cases who underwent sleeve gastrectomy

Creating pneumoperitoneum and port placement

After Veress needle insufflation in the left hypochondrium, the first 12-mm trocar for the camera was placed in the midpoint between the xiphoid and the umbilicus at midline. The second trocar (5 mm) was placed in the right hypochondrium at anterior axillary line; the third trocar (12 mm) was inserted in the left hypochondrium, symmetrical to the previous one. The fourth trocar (12 mm) was placed in the right quadrant at anterior clavicular line on the same level of the camera. A 5-mm incision in the subxiphoid region for hook liver retractor to elevate the left lobe of the liver.

Creation of the gastric tube

Dissection of greater omentum along the course of greater curvature of the stomach till liberating all of the greater curvature from fundus to pylorus. The gastric tube is created around an orogatric tube of 36-Fr size. The stomach is divided 4–5 cm from the pylorus with 60-mm Endo-GIA stapler. The first cartridge (Ethicon) used is green and then blue cartridges are used.

The remnant stomach is removed from 12-mm trocher, leak test is done using methylene blue while closing the stomach by the grasper at the level of pylorus, creating a high pressure in the gastric tube.

Liver biopsy

In both procedures, liver biopsy was taken from the left lobe of the liver using harmonic or cautery over Maryland grasper.

Postoperative follow-up

FibroScan was done to patients with positive liver biopsy for NASH immediately postoperative and after 1 year to compare between the effects of the two operations on NASH.

Measurements were performed in the right lobe of the liver through the intercostal spaces, with the patients lying in the dorsal decubitus position with their right arm in maximal abduction. The tip of the probe transducer covered with coupling gel was placed on the skin between the ribs at the level of the right lobe of the liver.

Liver-stiffness measurement of fibrosis and controlled attenuation parameter (CAP) measurement of steatosis was performed using FibroScan.

The CAP score is measured in decibels per meter (dB/m). It ranges from 100 to 400 dB/m. The fibrosis result is measured in kilopascals (kPa), it is normally between 2 and 6 kPa. The highest possible result is 75 kPa.

Statistical analysis

Patients' data were tabulated and processed using SPSS (26) statistical package for Windows 10. Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp.

Quantitative variables were expressed by means and SD and were analyzed using paired-sample t test.

Qualitative data were expressed by frequency and percent.

The results were significant when P value less than 0.05 and highly significant when P value less than 0.01.

Results

In our study, 14 (46.7%) patients underwent sleeve gastrectomy and 16 (53.3%) underwent MGB. There was no significant difference in age and sex in both groups. BMI was significantly higher in bypass group with mean of 55.69±5.50. In total, three patients were diabetic in the sleeve group compared with seven patients in the bypass group, with no significant difference in both groups (Table 1).

Regarding preoperative FibroScan, there was no significant difference between both groups regarding kPa and *f* score with P values 0.115 and 0.381, respectively, also, there was no significant difference regarding CAP and s score with P values 0.121 and 0.471, respectively (Table 2).

We also found that there were no significant differences regarding postoperative FibroScan data between the two groups (Table 3).

Table 1 Preoperative demographic data

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
Age (mean±SD)	34.36±12.24	36±7.36	0.452	0.655	NS
Sex [*n* (%)]					
Male	5 (35.7)	3 (18.8)	1.031	0.417	NS
Female	9 (64.3)	13 (81.3)			
BMI (mean±SD)	45.36±3.73	55.69±5.50	5.929	0.0000	HS
DM [*n* (%)]					
Yes	3 (21.4)	7 (43.8)	1.674	0.260	NS
No	11 (78.6)	9 (53.2)			

DM, diabetes mellitus.

On comparing kPa, CAP, and BMI preoperative and postoperative, there was a highly significant improvement in these parameters, both in sleeve (Table 4) and bypass patients (Table 5).

On comparing these improvements between the two groups, we found a significant difference in kPa improvement with mean difference of 1.89 ±0.96 in sleeve patients and mean of 2.92±0.95 in bypass patients and *P* value of 0.006. In addition, there was a significant difference in CAP improvement with mean of 70.14±26.09 in the sleeve group and mean of 95.75±37.54 in the bypass group with *P* value of 0.041. Regarding BMI improvement, there was a significant difference with the highest improvement in the bypass group 17.45±1.73 with *P* value of 0.021 (Table 6, Figs 1 and 2).

Regarding labs, there was a significant improvement in aspartate aminotransferase (AST), alanine aminotransferase (ALT), γ-glutamyl transferase, and triglycerides in both sleeve and bypass patients (Tables 4,5), but there were no significant

Table 2 Preoperative FibroScan

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
kPa (mean±SD)	8.84±2.73	10.40±2.52	1.624	0.115	NS
F score [*n* (%)]					
F1	4 (28.6)	2 (12.5)	3.208*	0.381	NS
F2	8 (57.1)	7 (43.8)			
F3	1 (7.1)	4 (25)			
F4	1 (7.1)	3 (18.8)			
CAP (mean±SD)	323.93±37.09	345.06±35.14	1.601	0.121	NS
S score [*n* (%)]					
S1	1 (7.1)	0	1.726*	0.471	NS
S2	3 (21.4)	2 (12.5)			
S3	10 (71.4)	14 (87.5)			

CAP, controlled attenuation parameter; kPa, kilopascal. *Comparing liver status by fibroscan pre and post operative.

Table 3 Postoperative FibroScan

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
kPa (mean±SD)	6.96±2.19	7.48±1.92	0.698	0.491	NS
F score [*n* (%)]					
F1	12 (85.7)	9 (56.3)	5.355*	0.088	NS
F2	1 (7.1)	5 (31.3)			
F3	0	2 (12.5)			
F4	1 (7.1)	0			
CAP (mean±SD)	253.79±18.36	249.31±13.96	0.757	0.455	NS
S score [*n* (%)]					
S1	10 (71.4)	15 (93.8)	1.609*	0.157	NS
S2	4 (28.6)	1 (6.3)			
S3	0	0			

CAP, controlled attenuation parameter; kPa, kilopascal. *Comparing liver status by fibroscan pre and post operative.

Table 4 Follow up of sleeve patients

Variables	Preoperative	Postoperative	Test value	*P* value	Significance
kPa (mean±SD)	8.85±2.73	6.96±2.19	7.339	0.000	HS
CAP (mean±SD)	323.93±37.09	253.79±18.36	10.061	0.000	HS
BMI (mean±SD)	45.36±3.73	30.07±2.06	20.333	0.000	HS
AST (mean±SD)	31.64±8.41	23.36±7.98	5.773	0.000	HS
ALT (mean±SD)	34±13.18	24.71±8.91	4.004	0.002	HS
TGS (mean±SD)	152.64±39.89	114.43±14.79	4.268	0.001	HS
GGT (mean±SD)	32.57±17.59	22.29±9.83	3.428	0.004	HS

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CAP, controlled attenuation parameter; GGT, γ-glutamyl transferase; kPa, kilopascal; TGS, triglycerides.

Table 5 Follow up of bypass patients

Variables	Preoperative	Postoperative	Test value	*P* value	Significance
kPa (mean±SD)	10.40±2.52	7.48±1.92	12.350	0.000	HS
CAP (mean±SD)	345.06±35.14	249.31±13.96	10.202	0.000	HS
BMI (mean±SD)	55.69±5.50	38.24±5.46	40.434	0.000	HS
AST (mean±SD)	34.25±15.07	23±9.58	3.561	0.003	HS
ALT (mean±SD)	32.50±14.34	20.38±5.84	4.048	0.001	HS
TGS (mean±SD)	137.88±39.19	101.44±10.74	3.993	0.001	HS
GGT (mean±SD)	24.81±8.08	18.81±5.86	5.477	0.000	HS

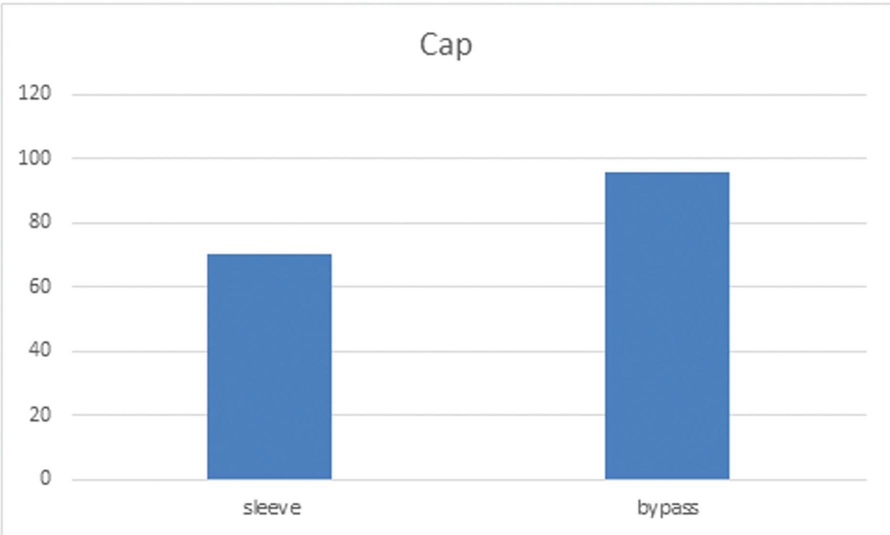
ALT, alanine aminotransferase; AST, aspartate aminotransferase; CAP, controlled attenuation parameter; GGT, γ-glutamyl transferase; kPa, kilopascal; TGS, triglycerides.

Table 6 FibroScan and BMI improvement

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
kPa (mean±SD)	1.89±0.96	2.92±0.95	2.962	0.006	HS
CAP (mean±SD)	70.14±26.09	95.75±37.54	2.138	0.041	S
BMI (mean±SD)	15.29±2.81	17.45±1.73	2.497	0.021	S

CAP, controlled attenuation parameter; kPa, kilopascal.

Figure 1



Comparison between CAP improvements in both groups. CAP, controlled attenuation parameter.

differences between sleeve and bypass patients regarding lab improvement (Table 7).

The operative time was significantly longer in the bypass group with 121.25±13.10 compared with sleeve group with *P* value of 0.000. Bleeding was minimal and there were no intraoperative complications (Table 8).

There was no significant difference in hospital stay between the two groups.

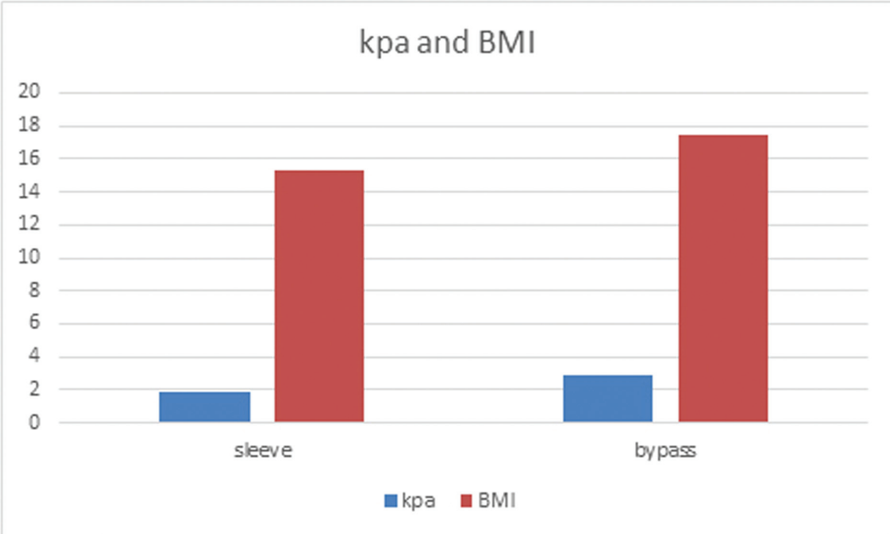
Only two patients had postoperative complications in the form of hemorrhage that was controlled conservatively, one in each group. There was no mortality (Table 8).

Discussion

NAFLD is the most common chronic liver disease in the general population. The prevalence rate can reach up to 90% in the morbidly obese population [6].

Accurate evaluation of the fibrosis stage is crucial in the management and follow-up of chronic liver diseases [7].

Figure 2



kPa and BMI improvement in both groups. kPa, kilopascal.

Table 7 Laboratory improvement

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
AST (mean±SD)	8.29±5.37	11.5±12.64	0.854	0.403	NS
ALT (mean±SD)	9.29±8.68	12.13±11.98	0.733	0.469	NS
TGS (mean±SD)	38.21±33.50	36.44±36.50	0.138	0.891	NS
GGT (mean±SD)	10.29±11.23	6±4.38	1.342	0.198	NS

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, γ-glutamyl transferase; TGS, triglycerides.

Table 8 Operative and postoperative data

Variables	Sleeve (*N*=14)	Bypass (*N*=16)	Test value	*P* value	Significance
Operative time (mean±SD)	59.29±8.29	121.25±13.10	15.214	0.000	HS
Hospital stay (mean±SD)	1.21±0.58	1.63±0.96	1.441	0.162	NS
Complications [*n* (%)]	1 (7.1)	1 (6.3)	0.096	1.000	NS
Hemorrhage [*n* (%)]	1 (7.1)	1 (6.3)	0.096	1.000	NS
Leak [*n* (%)]	0	0			

A significant number of NAFLD patients, especially those who underwent bariatric surgery, may develop liver fibrosis and even cirrhosis [8].

The gold-standard method for assessing fibrosis is a liver biopsy, however, sampling errors and serious complications such as bleeding limit its widespread use [9].

There are several noninvasive techniques for assessment of NASH. FibroScan has previously been considered difficult in a morbidly obese population with unreliable results or scan failure in up to 50% of patients [10].

This has led to higher rates of liver biopsy than may be necessary. Using the FibroScan XL probe and an experienced operator, we had a high success rate of 88% at baseline preoperative and 100% at follow-up, even with mean BMI in these groups being 40.2 and 28.7, respectively.

A number of recent reports using the XL probe have shown similar high success rates, confirming the utility of transient elastography even in extreme obesity [11].

Many studies used different modalities to study the effect of different bariatric procedures on NASH and to compare between these procedures to know which is better.

Froylich *et al.* [12] study made a comparison between the effect of Roux-en Y gastric bypass (RYGB) and sleeve gastrectomy on NALFD by using liver biopsy intraoperative and 18 months after the operation using ultrasound-guided biopsy. NAFLD activity score (NAS) and fibrosis stages were used to evaluate improvement in liver histology. The results showed that NAS after RYGB significantly improved in all morphologic characteristics, whereas only steatosis and total NAS improved after SG. Fibrosis state improved in both groups but to a greater degree after RYGB [12].

Baldwin *et al.* [13] conducted a systematic review and meta-analysis exclusively comparing RYGB and laparoscopic-sleeve gastrectomy (LSG) for amelioration of NAFLD using four separate criteria: ALT, AST, NAS, and NAFLD fibrosis score. It revealed that both RYGB and LSG significantly improved ALT, AST, NAS, and NAFLD fibrosis score postoperatively, but direct comparisons of RYGB to LSG in any of the four criteria failed to demonstrate superiority of any of these procedures [13].

In our study, both MGB and sleeve gastrectomy operations improved FibroScan values in patients after 1-year follow-up, but improvement in patients who underwent MGB was significantly better than patients who underwent sleeve gastrectomy.

Batman *et al.* [14] studied the effect of LSG on NAFLD by using the FibroScan to evaluate the state of liver fibrosis and steatosis preoperative, 3 and 6 months postoperative.

It showed a significant decrease in both kPa and CAP values after 6 months from operation. CAP value decreased from 309.2±68.7 to 240.4±85 dB/m with *P* value of 0.001, while kPa values decreased from 7.5±5.0 to 5.6±2.5 with *P* value of 0.013. After 3 months, only CAP showed significant improvement with *P* value of 0.001, but kPa showed nonsignificant decrease with *P* value of 0.0869.This suggested that LSG is associated with significant improvement in liver steatosis and fibrosis [14].

Also, in our study, there was improvement in both fibrosis and steatosis after 1 year of sleeve operation.

In a study done by Alsina *et al.* [15], they evaluated liver steatosis quantified by MRI and MR spectroscopy (MRS), in morbidly obese patients who underwent LSG.

All patients underwent a MRI and a MRS study 2 weeks before the intervention and 6 months after the surgery. The study revealed a significant reduction of liver steatosis demonstrated by reduction in the percentage of intrahepatic lipids and liver volume, determined by MRS and MRI [15].

Also, in our study, there was significant improvement in steatosis after sleeve operation proved by improvement of CAP value.

Endo *et al.* [16] used noncontrast computed tomography to measure liver : spleen ratio to study the effect of LSG on NAFLD. Computed tomography was done to all patients before the operation and 26 months after the operation. The study also showed significant improvement in liver : spleen ratio and a significant decrease in liver size, which supported the beneficial effect of LSG on NAFLD [16].

In our study, 49 patients who were suspected to be NASH by clinical, laboratory criteria, and intraoperative suspicious liver appearance underwent intraoperative liver biopsy. Of them, 30 patients proved to be NASH by biopsy, those patients were included in our study.

We combined liver biopsy and FibroScan, but liver biopsy was used only for confirmation of NASH and patients who were proved to be NASH by biopsy, underwent FibroScan immediately postoperative and after 1 year. This was done as postoperative liver biopsy carries high risk for complications.We found significant improvement in both CAP and kPa after 1 year in both bariatric procedures. CAP declined in sleeve from 323.93±37.09 to 253.79±18.36 with *P* value of 0.000 and in bypass declined from 345.06 ±35.14 to 249.31±13.96 with *P* value of 0.000. kPa declined in sleeve from 8.85±2.73 to 6.96±2.19 and in bypass patients declined from 10.40±2.52 to 7.48±1.92 with *P* value of 0.000. These results were consistent with the previous studies.

On comparing both operations, the improvement in both CAP and kPa was significantly higher in bypass patients with *P* value of 0.041 and 0.006, respectively, these results were consistent with Froylich *et al.* [12] study.

In addition, we found significant improvement in BMI in both groups with superiority for bypass over sleeve with *P* value of 0.021.

Regarding improvement in labs, we found significant improvement in both groups, but there were no significant differences in both groups.

The operative time was significantly longer in the bypass group with 121.25±13.10 compared with sleeve group with *P* value of 0.000. Bleeding was minimal and there were no intraoperative complications.

There was no significant difference in hospital stay between the two groups.

Only two patients had postoperative complications in the form of hemorrhage that was controlled conservatively, one in each group. There was no mortality.

There are some limitations to our study. First, we did not perform a liver biopsy for follow-up after 1 year in any of our patients concerning potential complications. Therefore, we could not compare the accuracy of FibroScan with liver biopsy to assess liver fibrosis. Second, our study population has a small sample size and short follow-up time.

Conclusion

The results of our study suggest that LSG and MGB are associated with significant improvement in liver steatosis and fibrosis with significant superiority for MGB over sleeve and FibroScan might be a useful adjunct to evaluate the effects of bariatric surgery on liver steatosis and fibrosis.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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